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<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 20481/0206861-US0
INTERNATIONAL APPLICATION NO. PCT/DK2004/000844		INTERNATIONAL FILING DATE 3 December 2004
TITLE OF INVENTION PHARMACEUTICAL COMPOSITIONS COMPRISING DANAZOL		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/581,170
APPLICANT(S) FOR DO/EO/US Per Holm et al.		PRIORITY DATE CLAIMED 3 December 2003

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/581,170</b>	INTERNATIONAL APPLICATION NO. <b>PCT/DK2004/000844</b>	ATTORNEY'S DOCKET NUMBER <b>20481/0206861-US0</b>
20. <input type="checkbox"/> Other items or information:		
The following fees have been submitted		
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... <b>\$310</b>	<b>CALCULATIONS</b> \$	<b>PTO USE ONLY</b>
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$0</b> All other situations ..... <b>\$210</b>	\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$0</b> Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... <b>\$100</b> International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... <b>\$410</b> All other situations ..... <b>\$510</b>	\$	
<b>TOTAL OF 21, 22 and 23 =</b>	\$ 0.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is <b>\$260</b> for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
- 100 =	/50 =	x <b>\$260.00</b>
Surcharge of <b>\$130</b> for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	- 20 =	0
Independent claims	9 - 3 =	5 PAID 1 UNPAID
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ + \$370
<b>TOTAL OF ABOVE CALCULATIONS =</b>		
\$ 105.00		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		
<b>SUBTOTAL =</b>		
\$ 105.00		
Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		
<b>TOTAL NATIONAL FEE =</b>		
\$ 105.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property +		
<b>TOTAL FEES ENCLOSED =</b>		
\$ 105.00		
<b>Amount to be refunded:</b>		\$
<b>Amount to be charged</b>		\$

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- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0100 . A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

**ADVISORY:** If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended paying fees online by using the electronic payment method.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

\_\_\_\_\_  
/FB/ Flynn Barrison (53,970)  
SIGNATURE

\_\_\_\_\_  
Robert C. Sullivan, Jr.  
NAME

CUSTOMER NUMBER: 07278

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